DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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November 12, 2015

Bio Concept Co., Ltd
c/o Ms. Diana Hong
General Manager
Mid-link Consulting Co., Ltd
P.O. Box 120-119
Shanghai, 200120
CHINA

Re: K150388
Trade/Device Name: Dental Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous dental implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: October 9, 2015
Received: October 13, 2015

Dear Ms. Hong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory, Infection
Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150388

Device Name
Dental Implant System

Indications for Use *(Describe)*
Dental implant systems are intended to be placed in the upper and lower jaw to support prosthetic devices and to restore a patient's chewing function. Dental implant systems are also indicated for immediate or early implantation following extraction or loss of natural teeth. Implants can be placed with immediate function on single-tooth and/or multiple tooth applications when good primary stability is achieved and with appropriate occlusal loading to restore chewing function. The prosthetic restorations used are single crowns, bridges and partial or full dentures, which are connected to the implants through the corresponding components (abutments). In cases of fully edentulous patients, 4 or more implants must be used in immediately loaded cases.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

This 510(k) Summary is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

The assigned 510(k) Number: K150388

1. Date of Preparation: 10/27/2015

2. Sponsor Identification

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3. Designated Submission Correspondent

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4. Identification of Proposed Device

Trade Name: Dental Implant System
Common Name: Endosseous dental implant
Model(s): TL and BL

Regulatory Information

Classification Name: Endosseous implant
Classification: II
Product Code: DZE
Secondary Product Code: NHA;
Regulation Number: 21 CFR 872.3640
Review Panel: Dental

Intended Use Statement:
Dental implant systems are intended to be placed in the upper and lower jaw to support prosthetic devices and to restore a patient's chewing function. Dental implant systems are also indicated for immediate or early implantation following extraction or loss of natural teeth. Implants can be placed with immediate function on single-tooth and/or multiple tooth applications when good primary stability is achieved and with appropriate occlusal loading to restore chewing function. The prosthetic restorations used are single crowns, bridges and partial or full dentures, which are connected to the implants through the corresponding components (abutments). In cases of fully edentulous patients, 4 or more implants must be used in immediately loaded cases.

Device Description

The proposed devices, Dental Implant Systems, are integrated systems of endosseous dental implants, which are intended to support prosthetic devices.

The systems are mainly available in two models which are Tissue Level (TL) and Bone Level (BL), each model consists of the following components: (1) Dental Implants, (2) Abutments, (3) Occlusal Screws and (4) Healing Caps. Each component is available in various configuration. In addition, the systems also consist of various specific surgical instruments.

Abutment models for TL dental implants include: Coping, Solid abutment, Retentive anchor abutment, Screw-retained abutment, Cementable abutment, Angled abutment.

Abutment models for BL dental implants include: Healing Abutment, Anatomic abutment, Meso abutment, Cementable abutment, Multi-base abutment.

5. Identification of Predicate Device(s)

510(k) Number: K123784
Product Name: STRAUMANN DENTAL IMPLANT SYSTEM

6. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- ISO 10993-3: 2006, Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
- ISO 10993-5,2009:Biological evaluation of medical devices - Part 5: Tests for in vitro Cytotoxicity
- ISO 10993-6 2007, Biological evaluation of medical devices - Part 6: Tests for local effects after implantation
- ISO 10993-10:2002/Amd1:2006, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization.
- ISO 10993-11: 2006, Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
- ISO 14801:2007, Dentistry - Implants - Dynamic fatigue test for endosseous dental implants
- USP 36-NF31, <85> Bacterial Endotoxins Test
- USP 36-NF31 <161>, Transfusion and Infusion Assemblies and Similar Medical Devices

Electronic speculum and energy spectrum of S-L-A microscopic surface test was conducted on proposed dental implant and predicate dental implant. The test result of scanning electron microscopy showed that there is no significant difference on microscopic morphology of S-L-A of test and controls samples. The test result of surface energy spectrum showed that there is no impurity on both test and control samples surface.

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Substantially Equivalent (SE) Comparison

Table 1 Comparison of Technology Characteristics

Item	Proposed Device(s)	Predicate Device(s)
Product Code:	DZE	DZE
Regulation #.	21 CFR 872.3640	21 CFR 872.3640
Class	II	II
Intended Use	Dental implant systems are intended to be placed in the upper and lower jaw to support prosthetic devices and to restore a patient's chewing function. Dental implant systems are also indicated for immediate or early implantation following extraction or loss of natural teeth. Implants can be placed with immediate function on single-tooth and/or multiple tooth applications when good primary stability is achieved and with appropriate occlusal loading to restore chewing function. The prosthetic restorations used are single crowns, bridges and partial or full dentures, which are connected to the implants through the corresponding components (abutments). In cases of fully edentulous patients, 4 or more implants must be used in immediately loaded cases.	Straumann® Dental implants are indicated for oral endosteal implantation in the upper and lower jaw arches for the functional and aesthetic oral rehabilitation of edentulous and partially dentate patients. Straumann® Dental implants are also indicated for immediate or early implantation following extraction or loss of natural teeth. Implants can be placed with immediate function on single-tooth and/or multiple tooth applications when good primary stability is achieved and with appropriate occlusal loading to restore chewing function. The prosthetic restorations used are single crowns, bridges and partial or full dentures, which are connected to the implants through the corresponding components (abutments). In cases of fully edentulous patients, 4 or more implants must be used in immediately loaded cases.
TL Dental Implants Systems		
Implant Type	Tissue Level	Tissue Level
Features	Standard	Standard
	Standard Plus	Standard Plus
	Tapered Effect	Tapered Effect
Neck	Narrow Neck	Narrow Neck
	Regular Neck	Regular Neck
	Wide Neck	Wide Neck
Abutment Connection	Standard / Tapered Effect: Internal Morse Taper, Internal Octagonal fixation	Standard / Tapered Effect: Internal Morse Taper, Internal Octagonal fixation
	Standard Plus External Octagonal Fixation	Standard Plus External Octagonal Fixation

Surface Treatment	Sand blasting process with large grit and acid-etching (SLA)	Sand blasting process with large grit and acid-etching (SLA)
Diameter of Dental Implants	3.3 mm / 4.1 mm / 4.8mm	3.3 mm / 4.1 mm / 4.8mm
Length of Dental Implants	8 / 10 / 12 / 14 / 16 mm	8 / 10 / 12 / 14 / 16 mm
Abutment Type	Solid, Angled, Screw-Retained, Cementable, Retentive Anchor	Solid, Angled, Screw-Retained, Cementable, Retentive Anchor
Angle	15° / 20°	15° / 20°
BL Dental Implants Systems		
Implant Type	Bone Level	Bone Level
Neck	No Neck	No Neck
Surface Treatment	Sand blasting process with large grit and acid-etching (SLA)	Sand blasting process with large grit and acid-etching (SLA)
Diameter of Dental Implants	3.3 mm / 4.1 mm / 4.8mm	3.3 mm / 4.1 mm / 4.8mm
Length of Dental Implants	8.2 / 10.2 / 12.2 / 14.2 mm	6 / 8 / 10 / 12 / 14 / 16 mm
Abutment Type	Solid, Angled, Cementable	Solid, Angled, Cementable
Angle	15° / 25°	15° / 25°
Safety		
Dental Implant	Titanium	Titanium
Abutment	Titanium Alloy (Ti-6AL-4V)	Titanium Alloy (Ti-6AL-4V)
Healing Cap Closure Screw	Titanium Alloy (Ti-6AL-4V)	Titanium Alloy (Ti-6AL-4V)
Sterilization		
Dental Implant	Provided in sterile condition, sterilized by radiation, SAL 10^{-6}	Provided in sterile condition, sterilized by radiation, SAL 10^{-6}
Abutment Healing Cap sure Screw	Provided in non-sterile condition, shall be sterilized by end user prior to operation via autoclave method, SAL 10^{-6}	Provided in non-sterile condition, shall be sterilized by end user prior to operation via autoclave method, SAL 10^{-6}

9. Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis above, the proposed devices are determined to be Substantially Equivalent (SE) to the predicate devices.